

HOUSE No. 4729

The Commonwealth of Massachusetts

HOUSE OF REPRESENTATIVES, March 7, 2006.

The committee on Public Health, to whom was referred the petition (accompanied by bill, House, No. 2689) of Peter J. Koutoujian and others for legislation to establish collaborative drug therapy management to improve pharmaceutical care for patients in Massachusetts, reports recommending that the accompanying bill (House, No. 4729) ought to pass.

For the committee,

PETER J. KOUTOUJIAN.

The Commonwealth of Massachusetts

In the Year Two Thousand and Six.

AN ACT TO ESTABLISH COLLABORATIVE DRUG THERAPY MANAGEMENT TO IMPROVE PHARMACEUTICAL CARE FOR PATIENTS IN MASSACHUSETTS.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

1 SECTION 1. Chapter 112, Section 24 of the General Laws as
2 appearing in the 2000 Official Edition, is hereby amended by
3 adding at the end thereof, the following:—

4 “Collaborative drug therapy management” means the initiating,
5 monitoring, modifying and discontinuing of a patient’s drug
6 therapy by a pharmacist in accordance with a collaborative prac-
7 tice agreement. Collaborative drug therapy management may
8 include: collecting and reviewing patient histories, obtaining and
9 checking vital signs, including pulse, temperature, blood pressure
10 and respiration; and under the supervision of, or in direct consul-
11 tation with a physician, ordering and evaluating the results of lab-
12 oratory tests directly related to drug therapy when performed in
13 accordance with approved protocols applicable to the practice set-
14 ting and providing such evaluation does not include any diag-
15 nostic component.

16 “Collaborative practice agreement” is a written and signed
17 agreement, entered into voluntarily, between a pharmacist with
18 advanced training and experience relevant to the scope of collabo-
19 rative practice and one or more supervising physicians that
20 defines the collaborative pharmacy practice in which the pharma-
21 cist and supervising physician(s) propose to engage. The collabo-
22 rative practice must be within the scope of practice of the
23 supervising physician(s). Each collaborative practice agreement
24 shall be subject to review and renewal on a biennial basis.

25 “Drug Regimen Review” includes but is not limited to the
26 following activities:

27 (a) Evaluations of the prescriptions and patient records for
28 known: allergies, rational therapy — contraindications, reasonable

29 dose and route of administration, reasonable directions for use,
30 and evaluation of the prescriptions and patient records for duplica-
31 tion therapy.

32 (b) Evaluation of prescriptions and patient records for interac-
33 tions: drug-drug, drug-food, drug-disease, adverse drug reactions
34 and idiosyncratic reactions.

35 (c) Evaluations of the prescriptions and patient records for
36 proper utilization (including over and under-utilization), and
37 optimum therapeutic outcomes.

1 SECTION 2. Chapter 94C, Section 7 (g) of the General Laws
2 as appearing in the Official Edition, is hereby amended by adding
3 at the end thereof, the following:—

4 The commissioner shall promulgate regulations that provide for
5 the registration of pharmacists, who have been duly registered in
6 accordance with section twenty-four of chapter one hundred and
7 twelve, to issue written prescriptions in accordance with guide-
8 lines mutually developed and agreed upon by the supervising
9 physician and the pharmacist in a collaborative practice agree-
10 ment, as defined in section 24 of chapter one hundred and twelve,
11 established in accordance with regulations of the Board of Regis-
12 tration in Medicine and Board of Registration in Pharmacy. Prior
13 to promulgating such regulations, the commissioner shall consult
14 with the Board of Registration in Medicine and Board of Registra-
15 tion in Pharmacy with regard to those schedules of controlled sub-
16 stances for which pharmacists may be registered.

1 SECTION 3. Chapter 112, Section 24B and Chapter 112,
2 Section 2 of the General Laws as appearing in the 2000 Official
3 Edition, is hereby amended by adding at the end thereof, the
4 following:—

5 The Board of Registration in Medicine and the Board of Regis-
6 tration in Pharmacy shall promulgate rules and regulations to
7 implement the provisions of this act. To aid in the implemen-
8 tation, the Board of Registration in Medicine and the Board of Reg-
9 istration in Pharmacy will consult with at least one individual
10 from each of the following groups: one individual to be an
11 employee of the Department of Public Health; one individual from
12 the Board of Registration in Medicine and one individual from the

13 Board of Registration in Pharmacy; one or more individuals from
14 Massachusetts Society of Health System Pharmacists, the Massa-
15 chusetts Chapter of the American Society of Consultant Pharma-
16 cists, the Massachusetts Pharmacists Association, the Long-Term
17 Care Pharmacy Alliance, the Massachusetts College of Pharmacy
18 and Health Sciences and the Bouve College of Health Sciences at
19 Northeastern University; and, one or more individuals from
20 Massachusetts Medical Society, the Massachusetts Chapter of the
21 American Medical Directors Association and the Massachusetts
22 Hospital Association. Said rules and regulations governing each
23 collaborative practice agreement shall include, but shall not be
24 limited to: (1) site and setting where the collaborative practice is
25 to take place; (2) qualifications of pharmacists and physicians par-
26 ticipating; (3) the role of any employed health care professional
27 with prescriptive privileges participating in the collaborative prac-
28 tice; (4) scope of conditions or diseases to be managed, the initial
29 list of which shall not include more than 5 disease states deemed
30 appropriate for collaborative management; (5) practice protocols;
31 (6) risk management activities; (7) documentation of any initia-
32 tion, modification and/or discontinuation of a patient's medication
33 therapy in the patient's permanent medical record; (8) outcome
34 measurements; and (9) informed consent procedures. The Board
35 of Registration in Medicine and the Board of Registration in Phar-
36 macy shall reconsider these regulations on a periodic basis as
37 deemed appropriate by the commissioner of the department of
38 public health for the purposes of adding or removing disease
39 states to be managed under collaborative drug therapy treatment,
40 as well as for the purpose of updating the rules and regulations
41 governing collaborative drug therapy treatment as necessary.

1 SECTION 4. Section 9 of said chapter 94C is hereby amended
2 by striking out paragraph (a), (b), (c), (d) and (e) as so appearing,
3 and inserting in place thereof the following:—

4 (a) A physician, dentist, podiatrist, optometrist as limited by
5 sections 66 and 66B of chapter 112 and paragraph (h) of section 7,
6 nurse practitioner and psychiatric nurse mental health clinical spe-
7 cialist as limited by paragraph (g) of said section 7 and section
8 80E of said chapter 112, physician assistant as limited by said
9 paragraph (g) of said section 7 and section 9E of said chapter 112,

10 a certified nurse-midwife as provided in section 80C of said
11 chapter 112, pharmacist as limited by said paragraph (g) of said
12 section 7 and section 24 of said chapter 112, or a veterinarian
13 when registered pursuant to the provisions of said section 7 and
14 acting in accordance with the provisions of applicable federal law
15 and any provision of this chapter which is consistent with federal
16 law, in good faith and in the course of a professional practice for
17 the alleviation of pain and suffering or for the treatment or allevia-
18 tion of disease, may possess such controlled substances as may
19 reasonably be required for the purpose of patient treatment and
20 may administer controlled substances or may cause the same to be
21 administered under his direction by a nurse.

22 (b) Notwithstanding the provisions of section 17, a physician,
23 physician assistant, dentist, podiatrist, optometrist, certified
24 nurse-midwife, nurse practitioner, psychiatric nurse mental health
25 clinical specialist, pharmacist as limited by said paragraph (g) of
26 said section 7 and section 24 of said chapter 112, or veterinarian
27 who is registered pursuant to the provisions of section 7, when
28 acting in good faith and in the practice of medicine, dentistry,
29 podiatry, optometry, nurse-midwifery, pharmacy, or veterinary
30 medicine or a nurse, when authorized by a physician, dentist,
31 podiatrist, optometrist, nurse practitioner, physician assistant, cer-
32 tified nurse-midwife, psychiatric nurse mental health clinical spe-
33 cialist or veterinarian in the course of such nurse's professional
34 practice, may dispense by delivering to an ultimate user, a con-
35 trolled substance in a single dose or in such quantity as is, in the
36 opinion of such physician, dentist, podiatrist, optometrist, nurse
37 practitioner, physician assistant, certified midwife, psychiatric
38 nurse mental health clinical specialist or veterinarian, essential for
39 the treatment of the patient; provided, however, that such amount
40 or quantity of such controlled substance shall not exceed the
41 amount needed for the immediate treatment of the patient and that
42 all such controlled substances required by the patient as part of
43 such treatment shall be dispensed by prescription to such ultimate
44 user in accordance with the provisions of this chapter. For the pur-
45 poses of this section, the words "amount needed for the immediate
46 treatment of the patient" shall mean the quantity of a controlled
47 substance which is necessary for the proper treatment of the
48 patient until it is possible for such patient to have a prescription
49 filled by a pharmacy.

50 This section shall not be construed to prohibit or limit the dis-
51 pensing of any prescription medication that is classified by the
52 department of public health as schedule VI and that is provided
53 free of charge by the manufacturer as part of an indigent patient
54 program or for use as samples if such prescription medications
55 are: (1) dispensed to the patient by a professional authorized to
56 dispense controlled substances pursuant to this section; (2) dis-
57 pensed in the package provided by the manufacturer; and (3) pro-
58 vided at no charge to the patient. The department shall promulgate
59 rules and regulations governing the dispensing of medication pur-
60 suant to this section. Said rules and regulations shall include, but
61 not be limited to, the types and amounts of medications that may
62 be dispensed and the appropriate safeguards for the labeling and
63 dispensing of such medications.

64 (c) A nurse who has obtained from a physician, dentist, physi-
65 cian assistant, podiatrist, certified nurse-midwife, nurse practi-
66 tioner, psychiatric nurse mental health clinical specialist,
67 pharmacist or veterinarian, a controlled substance for dispensing
68 to an ultimate user, pursuant to the provisions of paragraph (b) or
69 for administration to a patient pursuant to the provisions of para-
70 graph (a), during the absence of such physician, physician assis-
71 tant, dentist, podiatrist, certified nurse-midwife, nurse practitioner,
72 psychiatric nurse mental health clinical specialist, pharmacist or
73 veterinarian shall return to such physician, physician assistant,
74 dentist, podiatrist, certified nurse-midwife, nurse practitioner, psy-
75 chiatric nurse mental health clinical specialist, pharmacist or vet-
76 erinarian any unused portion of such substance which is no longer
77 required by the patient.

78 (d) Every physician, physician assistant, dentist, podiatrist, cer-
79 tified nurse-midwife, nurse practitioner or psychiatric nurse
80 mental health clinical specialist, pharmacist or veterinarian shall,
81 in the course of a professional practice, keep and maintain records
82 open to inspection by the commissioner during reasonable busi-
83 ness hours, which shall contain the names and quantities of any
84 controlled substances in Schedule I, II or III received by such
85 practitioner; the name and address of the patient to whom such
86 controlled substance is administered or dispensed; the name,
87 dosage and strength per dosage unit of such controlled substance
88 and the date of such administration or dispensing.

89 (e) Notwithstanding the provisions of paragraph (b), a physi-
90 cian, nurse practitioner, physician assistant, pharmacist as limited
91 by said paragraph (g) of said section 7 and section 24 of said
92 chapter 112, or certified nurse-midwife, when acting in good faith
93 and providing care under a program funded in whole or in part by
94 42 USC 300, or in a clinic licensed by the department to provide
95 comparable medical services or a registered nurse, registered pur-
96 suant to the provisions of section seventy-four of chapter one hun-
97 dred and twelve and authorized by such physician, nurse
98 practitioner, physician assistant, pharmacist as limited by said
99 paragraph (g) of said section 7 and section 24 of said chapter 112,
100 or certified nurse-midwife may lawfully dispense controlled sub-
101 stances pursuant to Schedule VI to recipients of such services in
102 such quantity as needed for treatment, and shall be exempt from
103 the requirement that such dispensing be in a single dosage or as
104 necessary for immediate treatment; provided, however, that such
105 registered nurse shall not so dispense except as provided in
106 section seventeen. The department may establish rules and regula-
107 tions controlling the dispensing of said medications including, but
108 not limited to, the types and amounts of medications dispensed
109 and appropriate safeguards for dispensing.